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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/350,899	07/12/99	TSUJI	K. 029650-080

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EXAMINER

CANELLA, K

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/350,899

Applicant(s)

Tsuji et al

Examiner

Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-13 and 15 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12, 13, and 15 is/are allowed.
- 6) ☒ Claim(s) 10 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 20) ☐ Other:

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*Response to Amendment*

1. Claim 14 has been canceled. Claims 10-13 and 15 have been amended. Claims 10-13 and 15 are under consideration.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

*New Rejections*

3. Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Stein and Goldenberg (Hybridoma, 1988, Vol. 7, pp. 555-567). Claims 10 and 11 are drawn to a glycoprotein antigen having the following characteristics:
  - (A)the antigen is expressed by human lung adenocarcinoma,
  - (B)the antigen exhibits a molecular weight of 200 kDa or more by SDS-PAGE under reducing conditions,
  - (C)the antigen is secreted by human lung adenocarcinoma,
  - (D)the antigen binds to the monoclonal antibodies produced by the following hybridomas: FERM BP-5383, FERM P-14879, FERM P-1488,
  - (E)the antigen reacts with the MAA and PSA lectins, but does not react with the GNA, SNA or DSA lectins.

Stein and Goldenberg disclose an antigen characterized from Calu3, human lung adenocarcinoma cell line, having a molecular weight of greater than 300 kDa. Stein and Goldenberg do not further characterize this antigen with respect to the binding of MAA, PNA, GNA, SNA or DSA lectins. The instant specification discloses that antibodies which bind the claimed antigen were obtained by using the culture broth of the Calu3 cell line, hence the antigen disclosed by Stein and Goldenberg may be the identical antigen of the instant invention, having the same inherent properties such as the binding particular lectins and monoclonal antibodies. The office does not have the facilities and resources to provide the factual evidence needed in order to

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establish that the antigen of the prior art does not possess the same material, structural and functional characteristics of the claimed antigen. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

4. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Gorbachev et al (*Biokhimiya*, 1994, Vol. 59, pp. 1401-1405) as evidenced by DeRobertis and DeRobertis (*Cell and Molecular Biology* (textbook), 7th Ed., 1975, pp. 235-237).. Claim 10 is drawn to a glycoprotein antigen having the following characteristics:

- (A) the antigen is expressed by human lung adenocarcinoma,
- (B) the antigen exhibits a molecular weight of 200 kDa or more by SDS-PAGE under reducing conditions,
- (C) the antigen is secreted by human lung adenocarcinoma,
- (D) the antigen binds to the monoclonal antibodies produced by the following hybridomas: FERM BP-5383, FERM P-14879, FERM P-1488.

Gorbachev et al discloses a glycoprotein antigen associated with human lung adenocarcinoma cells having a molecular weight of 400 kDa. Gorbachev et al does not specifically state that the antigen is secreted by the human lung adenocarcinoma cells, however, DeRobertis and DeRobertis teach that the fate of all glycoproteins is eventual exocytosis at the plasma membrane (De Robertis, figure 11-7), therefore all glycoproteins can be considered as secreted from cells. Gorbachev et al does not teach the binding of the monoclonal antibodies FERM BP-5383, FERM P-14879, FERM P-1488. However, the claimed antigen appears to be the same as the prior art antigen with respect to the binding of the monoclonal antibodies FERM BP-5383, FERM P-14879, FERM P-1488 as these monoclonal antibodies were selected on the basis of selective binding to human lung adenocarcinoma. The office does not have the facilities

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and resources to provide the factual evidence needed in order to establish that the antigen of the prior art does not possess the same material, structural and functional characteristics of the claimed antigen. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

5. All other rejections and objections as stated in Paper No. 3 are withdrawn.

*Conclusion*

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
ANTHONY C. CAPUTA  
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Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

May 19, 2001